DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION
Interim Final 2/5/99
RCRA Corrective Action
Environmental Indicator (EI) RCRIS code (CA750)

Migration of Contaminated Groundwater Under Control

Facility Name: **B. Braun Medical, Inc.**
Facility Address: **901 Marcon Boulevard, Allentown, PA 18109**
Facility EPA ID #: **PAD982679169**

1. Has all available relevant/significant information on known and reasonably suspected releases to the groundwater media, subject to RCRA Corrective Action (e.g., from Solid Waste Management Units [SWMU], Regulated Units [RU], and Areas of Concern [AOC]), been **considered** in this EI determination?

   [X] If yes – check here and continue with #2 below.

   [ ] If no – re-evaluate existing data, or

   [ ] If data are not available skip to #6 and enter "IN" (more information needed) status code.

BACKGROUND

Definition of Environmental Indicators (for the RCRA Corrective Action)

Environmental Indicators (EI) are measures being used by the RCRA Corrective Action program to go beyond programmatic activity measures (e.g., reports received and approved, etc.) to track changes in the quality of the environment. The two EI developed to-date indicate the quality of the environment in relation to current human exposures to contamination and the migration of contaminated groundwater. An EI for non-human (ecological) receptors is intended to be developed in the future.

Definition of "Migration of Contaminated Groundwater Under Control" EI

A positive "Migration of Contaminated Groundwater Under Control" EI determination ("YE" status code) indicates that the migration of "contaminated" groundwater has stabilized, and that monitoring will be conducted to confirm that contaminated groundwater remains within the original "area of contaminated groundwater" (for all groundwater "contamination" subject to RCRA corrective action at or from the identified facility (i.e., site-wide)).

Relationship of EI to Final Remedies

While Final remedies remain the long-term objective of the RCRA Corrective Action program the EI are near-term objectives which are currently being used as Program measures for the Government Performance and Results Act of 1993, GPRA). The "Migration of Contaminated Groundwater Under Control" EI pertains ONLY to the physical migration (i.e., further spread) of contaminated ground water and contaminants within groundwater (e.g., non-aqueous phase liquids or NAPLs). Achieving this EI does not substitute for achieving other stabilization or final remedy requirements and expectations associated with sources of contamination and the need to restore, wherever practicable, contaminated groundwater to be suitable for its designated current and future uses.

Duration / Applicability of EI Determinations

EI Determinations status codes should remain in RCRIS national database ONLY as long as they remain true (i.e., RCRIS status codes must be changed when the regulatory authorities become aware of contrary information).

2. Is **groundwater** known or reasonably suspected to be **"contaminated"**[1] above appropriately protective "levels" (i.e., applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action, anywhere at, or from, the facility?

____ If yes - continue after identifying key contaminants, citing appropriate "levels," and referencing supporting documentation.

X If no - skip to #8 and enter "YE" status code, after citing appropriate "levels," and referencing supporting documentation to demonstrate that groundwater is not "contaminated."

____ If unknown - skip to #8 and enter "IN" status code.

Rationale and Reference(s):
B. Braun Medical, Inc. (B. Braun), a privately-owned health care company, provides healthcare products and support services in the fields of drug delivery, intravenous (IV) therapy, pain control, clinical nutrition, dialysis, and vascular intervention. The company was founded in 1957. Prior to 1991, the company operated as Burron Medical Products, Inc.

The facility is situated in an industrial/office complex within the intersections of Marcon Boulevard and Postal Road with Irving Street. The property, 29.32 acres, is surrounded by office complex buildings to the immediate north, east, south and west. The facility generates wastes during the manufacturing and preparation of plastic disposable medical devices in a 360,000 square foot building at 901 Marcon Boulevard. On June 11 1990, the United States Environmental Protection Agency (USEPA) received Burron Medical Inc.'s initial Notification of Hazardous Waste Activity (PAD982679169) for the facility.

The facility generates wastes during the manufacturing and preparation of plastic disposable medical devices (there is no cleaning of medical devices; however, surface areas are wiped down to ensure cleanliness) and handled waste onsite for less than 90 days are covered under a permit-by-rule (PBR). The facility's elementary neutralization unit is located within the southern portion of the building which requires card access to the building and card access to the area of the neutralization unit. The unit consists of a 3,000-gallon aboveground storage tank (AST), two towers and a reaction tank. The entire unit is enclosed by cinder block walls on three sides and a six-inch high concrete curb on the fourth side.

The facility produces approximately 2,200 pounds of waste per month, making them a large quantity generator (LQG). Wastes identified for offsite disposal included: D001 (IPA, characteristically ignitable), D039 (tetrachloroethylene [PCE]), D008 (lead), D009 (mercury), D010 (selenium), and F002 (spent halogenated solvents including methylene chloride). As a by-product of the facility's closed-loop ethylene oxide sterilization emissions control system (deoxx scrubber system), the facility neutralizes the ethylene glycol process wastewater using sodium hydroxide. The neutralization waste is hazardous because of the corrosivity of the mixture (20% ethylene glycol and 80% water). The neutralized process water is transported offsite by others for ethylene glycol reuse.

A 4,000-gallon registered underground storage tank (UST) (Tank 001) receives ethylene glycol in the event of a spill from the floor drains throughout the area where ethylene oxide is used and from the deoxx scrubber system, and condensation from the sterilization units. The UST acts as an emergency catch basin if the manufacturing process malfunctions

A 4,000-gallon UST receives ethylene glycol in the event of a spill from the floor drains throughout the area where ethylene oxide is used and from the deoxx scrubber system, and condensation from the sterilization units. The UST acts as an emergency catch basin if the manufacturing process malfunctions.

No solid waste management units (SWMUs) or areas of concern (AOCs) were identified in available documents pertaining to the facility; however, a SWMU (the Hazardous Waste Accumulation Area) was identified during a site visit

[1] "Contamination" and "contaminated" describes media containing contaminants (in any form, NAPL and/or dissolved, vapors, or solids, that are subject to RCRA) in concentrations in excess of appropriate "levels" (appropriate for the protection of the groundwater resource and its beneficial uses).

that occurred on May 2, 2011. Wastes generated at the facility are stored in the hazardous waste accumulation area located on the north side of the building. Wastes generated at the facility include waste liquid solvents and solvent soaked rags used for preparation of the medical devices. The wastes generated in the laboratories and manufacturing areas are containerized in three-gallon containers or five gallon step cans. The wastes are moved nightly to a satellite storage area inside of the north corner of the facility, where they are combined into 55-gallon drums and ultimately transferred to the hazardous waste accumulation area. During the site visit, One 55-gallon drum containing solvent rags and one 55-gallon drum, Resource Conservation and Recovery Act (RCRA) empty, were observed in the satellite storage area. The hazardous waste accumulation area consists of a 10 foot by 20 foot self-contained steel modular shed that is kept locked. During the May 2, 2011 site visit, seven drums of hazardous waste and five empty, non-hazardous drums were observed inside of the shed. The shed was neat and orderly and no evidence of spills/releases was observed.

There have been no known/reported releases at this facility. The majority of the site is covered with impermeable surfaces (i.e., buildings, concrete, or asphalt paving).

Water and sewer are provided to the facility and surrounding area by the Catasauqua Municipal Water Works. According to the Catasauqua Borough's 2009 Annual Drinking Water Quality Report, water is derived entirely from three municipally owned and operated groundwater wells located within 1,200 feet of the water plant located at Walnut Street and St. Johns Street in Catasauqua. The wells ranged in depth from 141 feet below ground surface (bgs) to 235 feet bgs. The water plant is located approximately 1.6 miles northwest of the facility. Based on information obtained from the Pennsylvania Groundwater Information System (PaGWIS, accessed February 10, 2011), there is one open hole groundwater well located within a 0.5 mile radius of the facility. The well was installed in 1967 for the Bethlehem Steel Company. It is listed as a domestic well with a depth of 140 feet bgs.

B. Braun has a Watershed Protection Permit (Permit No. 07-03) through the Borough of Catasauqua for the disposal of industrial wastewater (including process and water treatment wastewaters from the extruders and water treatment units as well as sanitary wastewater) into the sanitary sewer. The permit is effective through November 9, 2012.

3. Has the **migration** of contaminated groundwater **stabilized** (such that contaminated groundwater is expected to remain within "existing area of contaminated groundwater"[2] as defined by the monitoring locations designated at the time of this determination)?

_____ If yes - continue, after presenting or referencing the physical evidence (e.g., groundwater sampling/measurement/migration barrier data) and rationale why contaminated groundwater is expected to remain within the (horizontal or vertical) dimensions of the "existing area of groundwater contamination"[2]).

_____ If no (contaminated groundwater is observed or expected to migrate beyond the designated locations defining the "existing area of groundwater contamination"[2]) - skip to #8 and enter "NO" status code, after providing an explanation.

_____ If unknown - skip to #8 and enter "IN" status code.

Rationale and Reference(s):

4. Does "contaminated" groundwater **discharge** into **surface water** bodies?

_____ If yes - continue after identifying potentially affected surface water bodies.

_____ If no - skip to #7 (and enter a "YE" status code in #8, if #7 = yes) after providing an explanation and/or referencing documentation supporting that groundwater "contamination" does not enter surface water bodies.

_____ If unknown - skip to #8 and enter "IN" status code.

Rationale and Reference(s):

[2] "existing area of contaminated groundwater" is an area (with horizontal and vertical dimensions) that has been verifiably demonstrated to contain all relevant groundwater contamination for this determination, and is defined by designated (monitoring) locations proximate to the outer perimeter of "contamination" that can and will be sampled/tested in the future to physically verify that all "contaminated" groundwater remains within this area, and that the further migration of "contaminated" groundwater is not occurring. Reasonable allowances in the proximity of the monitoring locations are permissible to incorporate formal remedy decisions (i.e., including public participation) allowing a limited area for natural attenuation.

5. Is the **discharge** of "contaminated" groundwater into surface water likely to be **"insignificant"** (i.e., the maximum concentration[3] of each contaminant discharging into surface water is less than 10 times their appropriate groundwater "level," and there are no other conditions (e.g., the nature, and number, of discharging contaminants, or environmental setting), which significantly increase the potential for unacceptable impacts to surface water, sediments, or eco-systems at these concentrations)?

_____ If yes - skip to #7 (and enter "YE" status code in #8 if #7 = yes), after documenting: 1) the maximum known or reasonably suspected concentration[3] of key contaminants discharged above their groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and 2) provide a statement of professional judgement/explanation (or reference documentation) supporting that the discharge of groundwater contaminants into the surface water is not anticipated to have unacceptable impacts to the receiving surface water, sediments, or eco-system.

_____ If no - (the discharge of "contaminated" groundwater into surface water is potentially significant) - continue after documenting: 1) the maximum known or reasonably suspected concentration[3] of each contaminant discharged above its groundwater "level," the value of the appropriate "level(s)," and if there is evidence that the concentrations are increasing; and 2) for any contaminants discharging into surface water in concentrations[3] greater than 100 times their appropriate groundwater "levels," the estimated total amount (mass in kg/yr) of each of these contaminants that are being discharged (loaded) into the surface water body (at the time of the determination), and identify if there is evidence that the amount of discharging contaminants is increasing.

_____ If unknown - enter "IN" status code in #8.

Rationale and Reference(s):

[3] As measured in groundwater prior to entry to the groundwater-surface water/sediment interaction (e.g., hyporheic) zone.

6. Can the **discharge** of "contaminated" groundwater into surface water be shown to be "**currently acceptable**" (i.e., not cause impacts to surface water, sediments or eco-systems that should not be allowed to continue until a final remedy decision can be made and implemented[4])?

____ If yes - continue after either: 1) identifying the Final Remedy decision incorporating these conditions, or other site-specific criteria (developed for the protection of the site's surface water, sediments, and eco-systems), and referencing supporting documentation demonstrating that these criteria are not exceeded by the discharging groundwater; OR
2) providing or referencing an interim-assessment,[5] appropriate to the potential for impact, that shows the discharge of groundwater contaminants into the surface water is (in the opinion of a trained specialists, including ecologist) adequately protective of receiving surface water, sediments, and eco-systems, until such time when a full assessment and final remedy decision can be made. Factors which should be considered in the interim-assessment (where appropriate to help identify the impact associated with discharging groundwater) include: surface water body size, flow, use/classification/habitats and contaminant loading limits, other sources of surface water/sediment contamination, surface water and sediment sample results and comparisons to available and appropriate surface water and sediment "levels," as well as any other factors, such as effects on ecological receptors (e.g., via bio-assays/benthic surveys or site-specific ecological Risk Assessments), that the overseeing regulatory agency would deem appropriate for making the EI determination.

____ If no - (the discharge of "contaminated" groundwater can not be shown to be "**currently acceptable**") - skip to #8 and enter "NO" status code, after documenting the currently unacceptable impacts to the surface water body, sediments, and/or eco-systems.

____ If unknown - skip to 8 and enter "IN" status code.

Rationale and Reference(s):

[4] Note, because areas of inflowing groundwater can be critical habitats (e.g., nurseries or thermal refugia) for many species, appropriate specialist (e.g., ecologist) should be included in management decisions that could eliminate these areas by significantly altering or reversing groundwater flow pathways near surface water bodies.

[5] The understanding of the impacts of contaminated groundwater discharges into surface water bodies is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration to be reasonably certain that discharges are not causing currently unacceptable impacts to the surface waters, sediments or eco-systems.

7. Will groundwater **monitoring** / measurement data (and surface water/sediment/ecological data, as necessary) be collected in the future to verify that contaminated groundwater has remained within the horizontal (or vertical, as necessary) dimensions of the "existing area of contaminated groundwater?"

_____ If yes - continue after providing or citing documentation for planned activities or future sampling/measurement events. Specifically identify the well/measurement locations which will be tested in the future to verify the expectation (identified in #3) that groundwater contamination will not be migrating horizontally (or vertically, as necessary) beyond the "existing area of groundwater contamination."

_____ If no - enter "NO" status code in #8.

_____ If unknown - enter "IN" status code in #8.

Rationale and Reference(s):

Migration of Contaminated Groundwater Under Control
Environmental Indicator (EI) RCRIS code (CA750)

8. Check the appropriate RCRIS status codes for the Migration of Contaminated Groundwater Under Control EI (event code CA750), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (attach appropriate supporting documentation as well as a map of the facility).

X YE Yes, "Migration of Contaminated Groundwater Under Control" has been verified. Based on a review of the information contained in this EI determination, it has been determined that the "Migration of Contaminated Groundwater" is "Under Control" at the **B. Braun Medical, Inc.** facility, EPA ID # **PAD982679169**, located at **901 Marcon Boulevard, Allentown, PA 18109**. Specifically, this determination indicates that the migration of "contaminated" groundwater is under control, and that monitoring will be conducted to confirm that contaminated groundwater remains within the "existing area of contaminated groundwater". This determination will be re-evaluated when the Agency becomes aware of significant changes at the facility.

____ NO - Unacceptable migration of contaminated groundwater is observed or expected.

____ IN - More information is needed to make a determination.

Completed by (signature) _____ Date _____

(print) _____

(title) _____

Supervisor (signature) _____ Date _____

(print) _____

(title) _____

(EPA Region or State) _____

Locations where References may be found:

USEPA Region III
Waste and Chemical Mgmt. Division
1650 Arch Street
Philadelphia, PA 19103

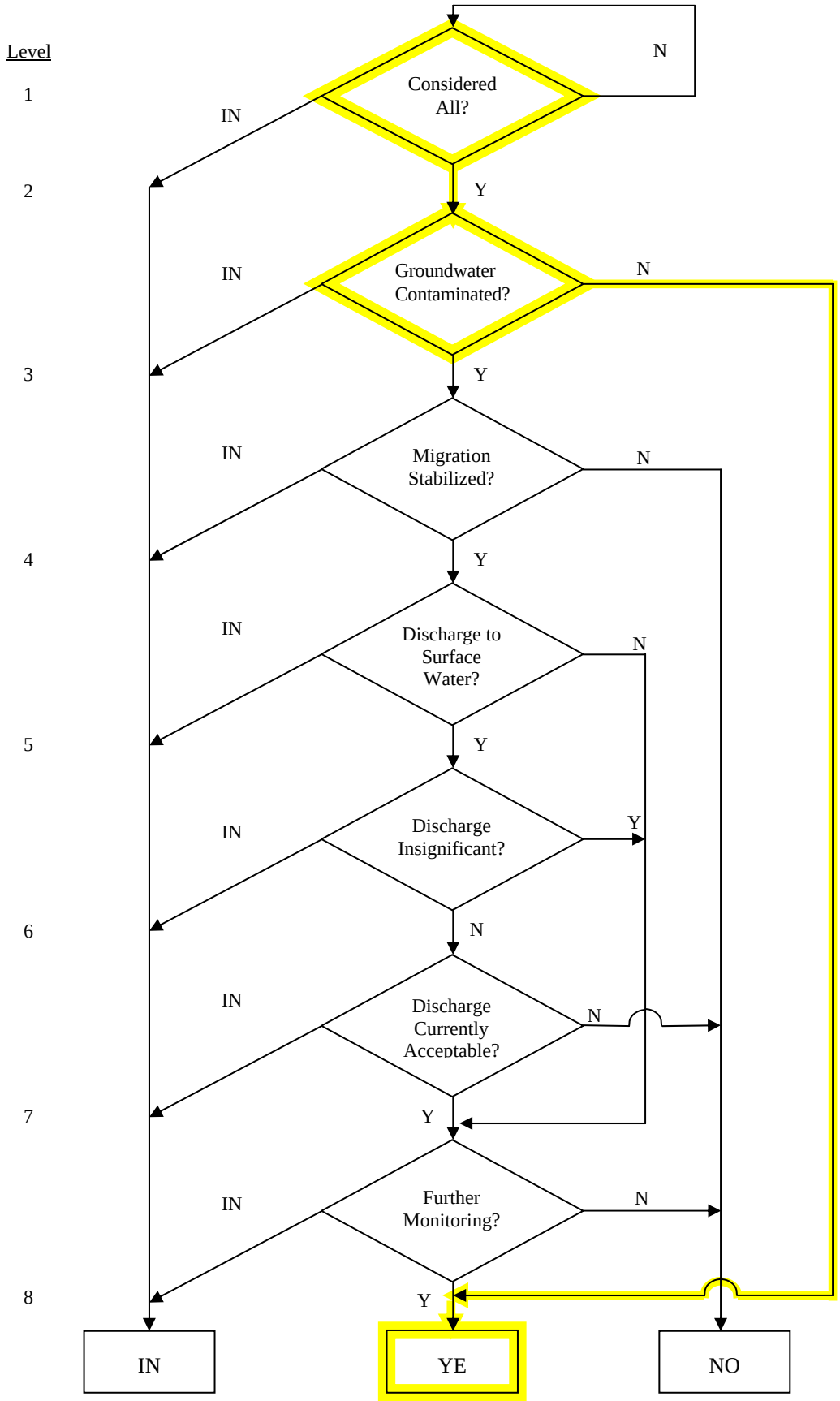
PADEP
North East Regional Office
2 Public Square
Wilkes-Barre, PA 18701

Contact telephone and e-mail numbers

(name) _____
(phone#) _____
(e-mail) _____

Facility Name:	B. Braun Medical, Inc.
EPA ID#	PAD982679169
City/State	Allentown, PA 18109

MIGRATION OF CONTAMINATED GROUNDWATER UNDER CONTROL (CA 750)



DOCUMENTATION OF ENVIRONMENTAL INDICATOR DETERMINATION
Interim Final 2/5/99
RCRA Corrective Action
Environmental Indicator (EI) RCRIS code (CA725)
Current Human Exposures Under Control

Facility Name: **B. Braun Medical, Inc.**
Facility Address: **901 Marcon Boulevard, Allentown, PA 18109**
Facility EPA ID #: **PAD982679169**

1. Has **all** available relevant/significant information on known and reasonably suspected releases to soil, groundwater, surface water/sediments, and air, subject to RCRA Corrective Action (e.g., from Solid Waste Management Units (SWMU), Regulated Units (RU), and Areas of Concern (AOC)), been **considered** in this EI determination?

   [X] If yes – check here and continue with #2 below.

   [ ] If no – re-evaluate existing data, or

   [ ] If data are not available skip to #6 and enter "IN" (more information needed) status code.

BACKGROUND

Definition of Environmental Indicators (for the RCRA Corrective Action)

Environmental Indicators (EI) are measures being used by the RCRA Corrective Action program to go beyond programmatic activity measures (e.g., reports received and approved, etc.) to track changes in the quality of the environment. The two EI developed to-date indicate the quality of the environment in relation to current human exposures to contamination and the migration of contaminated groundwater. An EI for non-human (ecological) receptors is intended to be developed in the future.

Definition of "Current Human Exposures Under Control" EI

A positive "Current Human Exposures Under Control" EI determination ("YE" status code) indicates that there are no "unacceptable" human exposures to "contamination" (i.e., contaminants in concentrations in excess of appropriate risk-based levels) that can be reasonably expected under current land- and groundwater-use conditions (for all "contamination" subject to RCRA corrective action at or from the identified facility [i.e., site-wide]).

Relationship of EI to Final Remedies

While Final remedies remain the long-term objective of the RCRA Corrective Action program the EI are near-term objectives which are currently being used as Program measures for the Government Performance and Results Act of 1993, GPRA). The "Current Human Exposures Under Control" EI are for reasonably expected human exposures under current land- and groundwater-use conditions ONLY, and do not consider potential future land- or groundwater-use conditions or ecological receptors. The RCRA Corrective Action program's overall mission to protect human health and the environment requires that Final remedies address these issues (i.e., potential future human exposure scenarios, future land and groundwater uses, and ecological receptors).

Duration / Applicability of EI Determinations

EI Determinations status codes should remain in RCRIS national database ONLY as long as they remain true (i.e., RCRIS status codes must be changed when the regulatory authorities become aware of contrary information).

Current Human Exposures Under Control
Environmental Indicator (EI) RCRIS code (CA725)

2. Are groundwater, soil, surface water, sediments, or air **media** known or reasonably suspected to be **"contaminated"**[1] above appropriately protective risk-based "levels" (applicable promulgated standards, as well as other appropriate standards, guidelines, guidance, or criteria) from releases subject to RCRA Corrective Action (from SWMUs, RUs or AOCs)?

	Yes	No	?	Rationale/Key Contaminants
Groundwater		**X**		No known/documented releases to groundwater from historical/present operations.
Air (indoors)[2]		**X**		No known/documented releases to soil/groundwater from historical/present operations.
Surface Soil (e.g., <2 ft)		**X**		No known/documented releases to soil from historical/present operations.
Surface Water		**X**		No known/documented releases from historical/present operations. Watershed Protection Permit No. 07-03.
Sediment		**X**		No known/documented releases from historical/present operations.
Subsurf. Soil (e.g., >2 ft)		**X**		No known/documented releases to soil from historical/present operations.
Air (outdoors)		**X**		No known releases at the facility. Facility emissions (under Title V air permit number 39-00055.

X If no (for all media) - skip to #6, and enter "YE," status code after providing or citing appropriate "levels," and referencing sufficient supporting documentation demonstrating that these "levels" are not exceeded.

____ If yes (for any media) - continue after identifying key contaminants in each "contaminated" medium, citing appropriate "levels" (or provide an explanation for the determination that the medium could pose an unacceptable risk), and referencing supporting documentation.

____ If unknown (for any media) - skip to #6 and enter "IN" status code.

Rationale and Reference(s):
B. Braun Medical, Inc. (B. Braun), a privately-owned health care company, provides healthcare products and support services in the fields of drug delivery, intravenous (IV) therapy, pain control, clinical nutrition, dialysis, and vascular intervention. The company was founded in 1957. Prior to 1991, the company operated as Burron Medical Products, Inc.

[1] "Contamination" and "contaminated" describes media containing contaminants (in any form, NAPL and/or dissolved, vapors, or solids, that are subject to RCRA) in concentrations in excess of appropriately protective risk-based "levels" (for the media, that identify risks within the acceptable risk range).

[2] Recent evidence (from the Colorado Dept. of Public Health and Environment, and others) suggest that unacceptable indoor air concentrations are more common in structures above groundwater with volatile contaminants than previously believed. This is a rapidly developing field and reviewers are encouraged to look to the latest guidance for the appropriate methods and scale of demonstration necessary to be reasonably certain that indoor air (in structures located above (and adjacent to) groundwater with volatile contaminants) does not present unacceptable risks.

The facility is situated in an industrial/office complex within the intersections of Marcon Boulevard and Postal Road with Irving Street. The property, 29.32 acres, is surrounded by office complex buildings to the immediate north, east, south and west. The facility generates wastes during the manufacturing and preparation of plastic disposable medical devices in a 360,000 square foot building at 901 Marcon Boulevard. On June 11 1990, the United States Environmental Protection Agency (USEPA) received Burron Medical Inc.'s initial Notification of Hazardous Waste Activity (PAD982679169) for the facility.

The facility generates wastes during the manufacturing and preparation of plastic disposable medical devices (there is no cleaning of medical devices; however, surface areas are wiped down to ensure cleanliness) and handled waste onsite for less than 90 days are covered under a permit-by-rule (PBR). The facility's elementary neutralization unit is located within the southern portion of the building which requires card access to the building and card access to the area of the neutralization unit. The unit consists of a 3,000-gallon aboveground storage tank (AST), two towers and a reaction tank. The entire unit is enclosed by cinder block walls on three sides and a six-inch high concrete curb on the fourth side.

The facility produces approximately 2,200 pounds of waste per month, making them a large quantity generator (LQG). Wastes identified for offsite disposal included: D001 (IPA, characteristically ignitable), D039 (tetrachloroethylene [PCE]), D008 (lead), D009 (mercury), D010 (selenium), and F002 (spent halogenated solvents including methylene chloride). As a by-product of the facility's closed-loop ethylene oxide sterilization emissions control system (deoxx scrubber system), the facility neutralizes the ethylene glycol process wastewater using sodium hydroxide. The neutralization waste is hazardous because of the corrosivity of the mixture (20% ethylene glycol and 80% water). The neutralized process water is transported offsite by others for ethylene glycol reuse.

A 4,000-gallon registered underground storage tank (UST) (Tank 001) receives ethylene glycol in the event of a spill from the floor drains throughout the area where ethylene oxide is used and from the deoxx scrubber system, and condensation from the sterilization units. The UST acts as an emergency catch basin if the manufacturing process malfunctions.

No solid waste management units (SWMUs) or areas of concern (AOCs) were identified in available documents pertaining to the facility; however, a SWMU (the Hazardous Waste Accumulation Area) was identified during a site visit that occurred on May 2, 2011. Wastes generated at the facility are stored in the hazardous waste accumulation area located on the north side of the building. Wastes generated at the facility include waste liquid solvents and solvent soaked rags used for preparation of the medical devices. The wastes generated in the laboratories and manufacturing areas are containerized in three-gallon containers or five gallon step cans. The wastes are moved nightly to a satellite storage area inside of the north corner of the facility, where they are combined into 55-gallon drums and ultimately transferred to the hazardous waste accumulation area. During the site visit, One 55-gallon drum containing solvent rags and one 55-gallon drum, Resource Conservation and Recovery Act (RCRA) empty, were observed in the satellite storage area. The hazardous waste accumulation area consists of a 10 foot by 20 foot self-contained steel modular shed that is kept locked. During the May 2, 2011 site visit, seven drums of hazardous waste and five empty, non-hazardous drums were observed inside of the shed. The shed was neat and orderly and no evidence of spills/releases was observed.

There have been no known/reported releases at this facility. The majority of the site is covered with impermeable surfaces (i.e., buildings, concrete, or asphalt paving).

Water and sewer are provided to the facility and surrounding area by the Catasauqua Municipal Water Works. According to the Catasauqua Borough's 2009 Annual Drinking Water Quality Report, water is derived entirely from three municipally owned and operated groundwater wells located within 1,200 feet of the water plant located at Walnut Street and St. Johns Street in Catasauqua. The wells ranged in depth from 141 feet below ground surface (bgs) to 235 feet bgs. The water plant is located approximately 1.6 miles northwest of the facility. Based on information obtained from the Pennsylvania Groundwater Information System (PaGWIS, accessed February 10, 2011), there is one open hole groundwater well located within a 0.5 mile radius of the facility. The well was installed in 1967 for the Bethlehem Steel Company. It is listed as a domestic well with a depth of 140 feet bgs.

B. Braun has a Watershed Protection Permit (Permit No. 07-03) through the Borough of Catasauqua for the disposal of industrial wastewater (including process and water treatment wastewaters from the extruders and water treatment units as well as sanitary wastewater) into the sanitary sewer. The permit is effective through November 9, 2012.

The nearest surface water body to the facility is a tributary to the Lehigh River located approximately 0.5 miles east of the facility. The tributary flows to the southwest and discharges to the Lehigh River approximately 1.2 miles downstream of the facility. There have been no known violations of the facility's NPDES permit.

B. Braun currently operates under a Title V air permit (permit number 39-00055) which is effective through January 12, 2015.

3. Are there **complete pathways** between "contamination" and human receptors such that exposures can be reasonably expected under the current (land- and groundwater-use) conditions?

Summary Exposure Pathway Evaluation Table

	Potential **Human Receptors** (Under Current Conditions)						
Contaminated Media	Residents	Workers	Day-Care	Construction	Trespassers	Recreation	Food[3]
Groundwater							
Air (indoors)							
Soil (surface, e.g., <2 ft.							
Surface Water							
Sediment							
Soil (subsurface e.g., >2 ft.							
Air (outdoors)							

Instructions for Summary Exposure Pathway Evaluation Table:

1. Strike-out specific Media including Human Receptors' spaces for Media which are not "contaminated" as identified in #2 above.

2. enter "yes" or "no" for potential "completeness" under each "Contaminated" Media -- Human Receptor combination (Pathway).

Note: In order to focus the evaluation to the most probable combinations some potential "Contaminated" Media - Human Receptor combinations (Pathways) do not have check spaces ("___"). While these combinations may not be probable in most situations they may be possible in some settings and should be added as necessary.

_____ If no (pathways are not complete for any contaminated media-receptor combination) - skip to #6, and enter "YE" status code, after explaining and/or referencing condition(s) in-place, whether natural or man-made, preventing a complete exposure pathway from each contaminated medium (e.g., use optional Pathway Evaluation Work Sheet to analyze major pathways).

_____ If yes (pathways are complete for any "Contaminated" Media - Human Receptor combination) - continue after providing supporting explanation.

_____ If unknown (for any "Contaminated" Media - Human Receptor combination) - skip to #6 and enter "IN" status code.

Rationale and Reference(s):

[3] Indirect Pathway/Receptor (e.g., vegetables, fruits, crops, meat and dairy products, fish, shellfish, etc.

4. Can the **exposures** from any of the complete pathways identified in #3 be reasonably expected to be **"significant"**[4] (i.e., potentially "unacceptable" because exposures can be reasonably expected to be: 1) greater in magnitude (intensity, frequency and/or duration) than assumed in the derivation of the acceptable "levels" (used to identify the "contamination"); or 2) the combination of exposure magnitude (perhaps even though low) and contaminant concentrations (which may be substantially above the acceptable "levels") could result in greater than acceptable risks)?

____ If no (exposures can not be reasonably expected to be significant (i.e., potentially "unacceptable") for any complete exposure pathway) - skip to #6 and enter "YE" status code after explaining and/or referencing documentation justifying why the exposures (from each of the complete pathways) to "contamination" (identified in #3) are not expected to be "significant."

____ If yes (exposures could be reasonably expected to be "significant" (i.e., potentially "unacceptable") for any complete exposure pathway) - continue after providing a description (of each potentially "unacceptable" exposure pathway) and explaining and/or referencing documentation justifying why the exposures (from each of the remaining complete pathways) to "contamination" (identified in #3) are not expected to be "significant."

____ If unknown (for any complete pathway) - skip to #6 and enter "IN" status code

Rationale and Reference(s):

5. Can the "significant" **exposures** (identified in #4) be shown to be within **acceptable** limits?

____ If yes (all "significant" exposures have been shown to be within acceptable limits) - continue and enter "YE" after summarizing and referencing documentation justifying why all "significant" exposures to "contamination" are within acceptable limits (e.g., a site-specific Human Health Risk Assessment).

____ If no (there are current exposures that can be reasonably expected to be "unacceptable") - continue and enter "NO" status code after providing a description of each potentially "unacceptable" exposure.

____ If unknown (for any potentially "unacceptable" exposure) - continue and enter "IN" status code

Rationale and Reference(s):

[4] If there is any question on whether the identified exposures are "significant" (i.e., potentially "unacceptable") consult a human health Risk Assessment specialist with appropriate education, training and experience.

6. Check the appropriate RCRIS status codes for the Current Human Exposures Under Control EI event code (CA725), and obtain Supervisor (or appropriate Manager) signature and date on the EI determination below (and attach appropriate supporting documentation as well as a map of the facility):

X YE – Yes, "Current Human Exposures Under Control" has been verified. Based on a review of the Information contained in this EI Determination, "Current Human Exposures" are expected to be "Under Control" at the **B. Braun Medical, Inc.** facility, EPA ID # **PAD982679169**, located at **901 Marcon Boulevard, Allentown, PA 18109** under current and reasonably expected conditions. This determination will be re-evaluated when the Agency/State becomes aware of significant changes at the facility.

____ NO - "Current Human Exposures" are NOT "Under Control."

____ IN - More information is needed to make a determination.

Completed by (signature) _____ Date _____

(print) _____

(title) _____

Supervisor (signature) _____ Date _____

(print) _____

(title) _____

(EPA Region or State) _____

Locations where References may be found:

USEPA Region III
Waste and Chemical Mgmt. Division
1650 Arch Street
Philadelphia, PA 19103

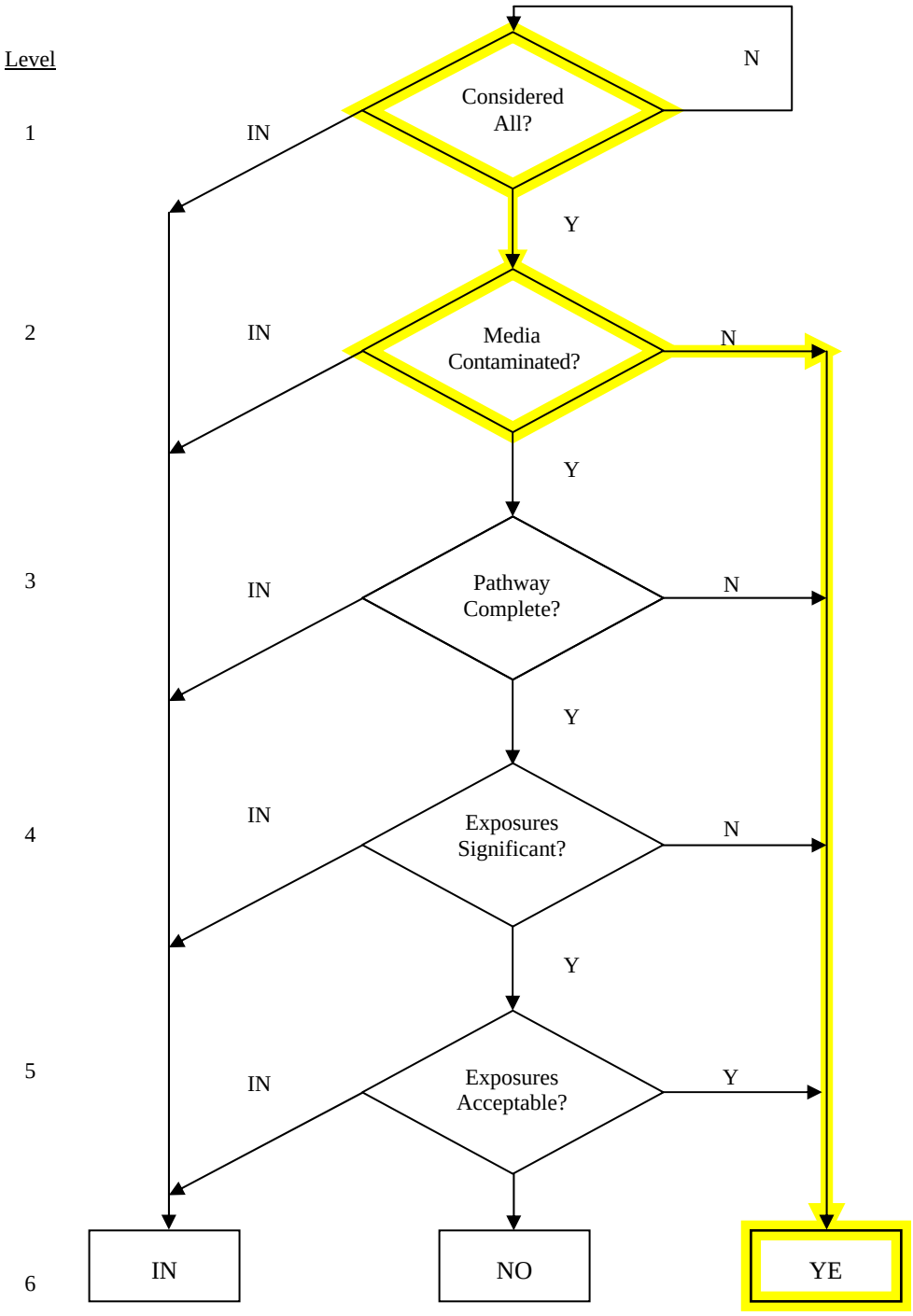
PADEP
North East Regional Office
2 Public Square
Wilkes-Barre, PA 18701

Contact telephone and e-mail numbers
(signature) _____
(print) _____
(title) _____

FINAL NOTE: THE HUMAN EXPOSURES EI IS A QUALITATIVE SCREENING OF EXPOSURES AND THE DETERMINATIONS WITHIN THIS DOCUMENT SHOULD NOT BE USED AS THE SOLE BASIS FOR RESTRICTING THE SCOPE OF MORE DETAILED (E.G., SITE-SPECIFIC) ASSESSMENTS OF RISK.

Facility Name:	B. Braun Medical, Inc.
EPA ID#	PAD982679169
City/State	Allentown, PA 18109

CURRENT HUMAN EXPOSURES UNDER CONTROL (CA725)



United States Environmental Protection Agency
Region III
Corrective Action Program

Environmental Indicator Inspection Report
For

B. Braun Medical, Inc.
901 Marcon Boulevard
Allentown, PA 18109

EPA ID No. PAD982679169

Prepared By

Baker

September 2011

TABLE OF CONTENTS

LIST OF APPENDICES

RCRA SITE INSPECTION REPORT

Purpose: To gather relevant information from B. Braun Medical, Inc. (B. Braun) or (facility) in order to determine whether human exposures and groundwater releases are controlled, as per Environmental Indicator (EI) Determination forms.

Documentation Review: Prior to the site visit, Michael Baker Jr., Inc. (Baker) personnel conducted an extensive records review of the Pennsylvania Department of Environmental Protection (PADEP) Northeast Regional Office and the United States Environmental Protection Agency (USEPA) Region III Philadelphia Office files. Additional information was provided by the facility subsequent to the site visit to provide clarification relative to the facility's permits.

Attendees at Site Visit:

Name	Organization	Phone Number	E-Mail address
William Feher	PADEP	570-826-2273	wfeher@pa.gov
Jim Mack	B. Braun	610-266-0500	jim.mack@bbraun.com
Stephen S. Stancick	B. Braun	610-596-2441	steve.stancick@bbraun.com
Chip Marshall	B. Braun	610-266-0500	chip.marshall@bbraun.com
Michael Bartholomew	B. Braun	610-266-0500	mike.bartholomew@bbraun.com
Rex Boland	B. Braun	610-596-2870	rex.boland@bbraun.com
Tina Entenman	Baker	717-221-2061	tentenman@mbakercorp.com

Meeting Summary: A meeting at the facility was held with the attendees noted above on May 2, 2011. Ms. Entenman, PG presented the facility with information regarding USEPA Region III's Corrective Action process, the EI Assessment Program and the legislation driving this program. Under this investigation, USEPA Region III is focusing on two interim EIs to evaluate whether any unacceptable risk to human health and/or the environment is ongoing at each priority facility. The two indicators are determining if human exposures are controlled and groundwater releases are controlled. Prior to and during the site visit, outstanding issues and discrepancies encountered in the file review summary were discussed.

The site visit continued with an overview of areas to be observed and a tour of the facility. Photographs of the facility are presented in Appendix A: Photographs.

A. Location and Operational History of the Facility, Including all Wastes Generated at the Facility and their Management

Site Layout and Background Information

Site Layout

The facility is situated in an industrial/office complex within the intersections of Marcon Boulevard and Postal Road with Irving Street. The property, 29.32 acres, is surrounded by office complex buildings to the immediate north, east, south and west. An airport tarmac for the Lehigh Valley International Airport is located immediately northwest of the facility. The nearest residential subdivision is located 0.3 miles south of the facility, adjacent the Cedar Hill Memorial Park (cemetery). The facility is located approximately 0.25 miles north of US Route 22 and approximately 0.85 miles east of the Route 987 (Airport Road) interchange (Appendix B: Figure 1 - Facility Location Map). The Lehigh River is located 0.8 miles west of the facility.

According to the Lehigh County property assessment website (accessed March 15, 2011), the original 285,000 square foot building at 901 Marcon Boulevard was constructed in 1985. A 75,000 square foot structure was added in 2009. The property was owned by Burron Medical, Inc. from 1984 to 1994 when it was purchased by B. Braun who currently owns the property. In 2006, B. Braun purchased the property directly east of their operating facility, 939 Marcon Boulevard, for future expansion. To date, this building is used only for meetings and conferences and storage of documents/supplies.

The facility's elementary neutralization unit (deoxx scrubber system) is located within the southern portion of the building which requires card access to the building and card access to the area of the neutralization unit (Appendix B: Figure 2 - Facility Layout). The unit consists of a 3,000-gallon aboveground storage tank (AST), two towers and a reaction tank. The entire unit is enclosed by cinder block walls on three sides and a concrete curb that is approximately 1.5 feet high on the fourth side.

In February 2001, the waste accumulation area was located on the east side of the facility, just outside of the main building. The waste accumulation area is currently located on the north end of the property adjacent to the building. The area is surrounded by a six-foot high chain link fence with two gated and locked entrances. Two modular storage units are present within the

waste accumulation area. The units are approximately 10 feet by 20 feet in size. The southern unit stores raw materials in 55-gallon drums including various percentage grades of isopropyl alcohol (IPA), methylene chloride (MeCl), tetrahydrofuran (THF), cyclohexane, and MTM, a mixture of MeCl and THF. Two grades of MTM are used at the facility that include 75% MeCl to 25% THF, and 50% MeCl to 50% THF. The northern unit stores both hazardous and non-hazardous waste materials primarily contained in 55-gallon drums (Hazardous Waste Accumulation Area).

Ownership Information

B. Braun Medical, Inc., a privately-owned health care company, provides healthcare products and support services in the fields of drug delivery, intravenous (IV) therapy, pain control, clinical nutrition, dialysis, and vascular intervention. The company was founded in 1957. Prior to 1991, the company operated as Burron Medical Products, Inc. Currently, B. Braun Medical, Inc. operates as a subsidiary of B. Braun Melsungen AG, with its United States corporate headquarters located at 824 12th Avenue, Bethlehem, Pennsylvania (3,500 employees). Burron Medical, Inc. had a separate USEPA identification (ID) number (No.), PAD002397347, for the 824 12th Avenue facility. In 2006, the company purchased the former SureFit, Inc. property located at 939 Marcon Boulevard, directly east of its operating facility, with plans for future expansion of its operations. To date, this building is used only for meetings and conferences and storage of documents/supplies.

In July 1998, the company was also operating as B. Braun Biotech, Inc. (BBI). BBI operated at 999 Postal Road, Allentown, Pennsylvania, and was subsequently acquired by Sartorius AG in 2000. In 2008, the facility at 999 Postal Road was closed. According to USEPA's Envirofacts, BBI is listed as a small quantity generator (SQG) under PAD987378494.

Waste

The facility generates wastes during the manufacturing and preparation of plastic disposable medical devices (there is no cleaning of medical devices; however, surface areas are wiped down to ensure cleanliness). The facility also handles waste onsite for less than 90 days under a permit-by-rule (PBR). It was noted that the facility produced approximately 2,200 pounds of waste per month, making them a large quantity generator (LQG). Hazardous wastes identified for offsite disposal included: D001 (IPA, characteristically ignitable), D039 (tetrachloroethylene [PCE]), D008 (lead), D009 (mercury), D010 (selenium), and F002 (spent halogenated solvents including

MeCl).

As a by-product of the facility's closed-loop ethylene oxide sterilization emissions control system (deoxx scrubber system) (Appendix B: Figure 2 - Facility Layout), the facility neutralizes ethylene glycol process wastewater using sodium hydroxide. The pH of the glycol solution is low (< 2.0) prior to the addition of sodium hydroxide which increases the pH, ranging from 5 to 9. The neutralization waste is hazardous because of the corrosivity of the mixture (20% ethylene glycol and 80% water). The neutralized process water is transported offsite by others for ethylene glycol reuse. The material is shipped to a recycler who reblends it and sells it as antifreeze. B. Braun receives no monetary compensation for the ethylene glycol. A preventative maintenance program is maintained for the entire sterilization area.

Ethylene oxide (EtO) is received in pressurized drums. The drums are stored in a room adjacent to the deoxx scrubber system (Appendix B: Figure 2 - Facility Layout). When the ethylene oxide drums are spent, they are stored in a fenced and locked storage area outside of the ethylene oxide room until they are picked up by an outside vendor. The ethylene oxide is pumped into eight separate humidified rooms (sterilizer units) where medical devices are sterilized. (Note: There are floor drains in each sterilizer unit and throughout the areas where ethylene oxide is used. The floor drains are present to capture releases that may occur and direct them into the 4,000-gallon underground storage tank (UST) (Tank 001) located outside of the ethylene oxide spent drum storage area. Condensation from the sterilizer units is also directed to the UST via these floor drains. There is only one floor drain that does not discharge to the UST. This floor drain is elevated six inches off of the floor and discharges directly to the sanitary sewer system.)

The medical devices are then aerated to remove the ethylene oxide. The ethylene oxide is directed to the deoxx scrubber system, which operates as follows: ethylene oxide gas stream enters the bottom of Tower 1, acidic water enters the top of Towers 1 and 2, and entrapment occurs when ethylene oxide mixes with the acidic water. Added efficiency occurs through Tower 2. The final EtO/acidic water mixture goes to the reaction tank. Mixing of the EtO/acidic water converts the mixture to ethylene glycol and water. The ethylene glycol mixture is re-circulated back to the 3,000-gallon AST. The storage tank liquid (sulfuric acid and water) is reused until the tank is full or the concentration reaches 50%. According to facility representatives, approximately 4,000 to 5,000 gallons of ethylene glycol is reclaimed every six weeks.

Ethylene oxide is also directed to the catalytic oxidizer located on the west side of the facility which converts the ethylene oxide to carbon dioxide and water. The catalytic oxidizer is equipped with a heat recovery unit. The heat is directed back into the aeration unit.

On June 11 1990, the USEPA received Burron Medical Inc.'s initial Notification of Hazardous Waste Activity (PAD982679169) for the 901 Marcon Boulevard facility.

On May 5, 1997, B. Braun submitted a Notification of Hazardous Waste Activity (dated May 7, 1997). Listed wastes included: D001 (characteristically ignitable), F002 and F003 (spent halogenated solvents), D002 (characteristically corrosive), D010 (selenium), and D011 (silver). In the cover letter, the company stated they had changed their name from Burron Medical to B. Braun Medical, Inc. and that they changed from a SQG to a LQG. According to the USEPA's Envirofacts, B. Braun is an active treatment, storage and disposal (TSD) facility, an active LQG, and an active Universal Waste Handler under PAD982679169 (Resource Conservation and Recovery Act Information System [RCRIS] Hazardous Waste Program).

The facility is also a LQG of residual wastes including: waste plastic, returned medical products, paper and other debris. Plastic is shredded prior to disposal. Returned medical products are not shredded, but landfilled as special handling waste. Annual reports (Form 26R) are routinely submitted to PADEP by the facility.

An inventory of the documents and references used in this EI report is provided in Appendix C.

Permit and Regulatory Action History

Waste

On June 11 1990, the USEPA received Burron Medical Inc.'s initial Notification of Hazardous Waste Activity (PAD982679169) for the 901 Marcon Boulevard facility.

On April 30, 1997, B. Braun sent a letter to PADEP indicating that it was brought to their attention that they were required to apply for a PBR because of the neutralization process of ethylene glycol (25 PA Code 265.433, Neutralization Treatment Units). The letter included a description of their process. On June 6, 1997, PADEP noted their receipt of the submittal and the PADEP inspection that occurred April 17, 1997. Based on the documentation and the inspection,

PADEP determined that the treatment unit qualified for PBR.

On June 9, 1997, PADEP replied to B. Braun's submittal requesting an approval to operate a captive wastewater treatment unit.

On February 28, 2002, the facility responded to PADEP regarding their yearly compliance audit (January 30, 2002) by forwarding their 2001 Hazardous Waste Biennial Report and notifying them of management changes.

Air

In a PADEP letter dated January 14, 2010, B. Braun received their currently active Title V air permit (permit number 39-00055) which was issued on January 13, 2010, and is effective through January 12, 2015. The permit was renewed on March 16, 2010 to incorporate the emissions sources for 939 Marcon Boulevard previously permitted under 39-00038. Emissions sources included under the permit are two boilers, four emergency generators, two fire pumps, eight sterilizers, the aeration room, the catalytic oxidizer, and the deoxx unit.

According to the eFACTs website, routine air quality inspections and administrative file reviews were conducted for the facility from 1997 through 2011 with no violations noted except as follows:

- August 27, 2002 resulting in a Notice of Violation (NOV) issued on August 28, 2002

- October 28, 2002 resulting in a NOV issued on November 1, 2002 and a Consent Assessment of Civil Penalty executed on April 15, 2003 for which a fine was levied. Documentation from the PADEP indicated that the referenced NOV and Consent Assessment of Civil Penalty was rescinded by the Department.

- July 23, 2004 resulting in a NOV issued on July 26, 2004 for operating the catalytic oxidizer below the permitted temperature from November 26, 2002 until August 28, 2003. During an August 17, 2005 meeting with PADEP, it was noted that in November of 2001 the USEPA amended 40 CFR Part 63, Ethylene Oxide Emissions Standards for Sterilization Facilities, and removed the requirement to operate at the average temperature to demonstrate continuous compliance. The USEPA now required facilities to maintain a minimum temperature for catalytic oxidizers, based on manufacture design,

and perform a work practice. B. Braun re-submitted the temperature charts in the proper scale; subsequently, the NOV was rescinded on November 1, 2005.

NPDES

B. Braun has a Watershed Protection Permit (Permit No. 07-03) through the Borough of Catasauqua for the disposal of industrial wastewater (including process and water treatment wastewaters from the extruders and water treatment units as well as sanitary wastewater) into the sanitary sewer. The permit is effective from November 10, 2007 through November 9, 2012.

B. Description of all Solid Waste Management Units (SWMU)s and/or Areas of Concern (AOCs)

SWMUs

No SWMUs or AOCs were identified in the documents reviewed for the EI; however, a SWMU was identified during the site visit.

Hazardous Waste Accumulation Area

As previously discussed, wastes generated at the facility are stored in the hazardous waste accumulation area located on the north side of the building (Appendix B: Figure 2 - Facility Layout). Wastes generated at the facility include waste liquid solvents and solvent soaked rags used for preparation of the medical devices. The wastes generated in the laboratories and manufacturing areas are containerized in three-gallon containers or five gallon step cans. The wastes are moved nightly to a satellite storage area inside of the north corner of the facility, where they are combined into 55-gallon drums and ultimately transferred to the hazardous waste accumulation area. During the site visit, one 55-gallon drum containing solvent rags and one 55-gallon drum, RCRA empty, were observed in the satellite storage area. The hazardous waste accumulation area consists of a 10 foot by 20 foot self-contained steel modular shed that is kept locked. During the site visit, seven drums of hazardous waste and five empty, non-hazardous drums were observed inside the shed. The shed was neat and orderly and no evidence of spills/releases was observed.

Storage Tanks

On May 31, 2000, PADEP conducted a storage system visit to verify if piping associated with the new, registered 4,000-gallon UST (Tank 001) was double walled (steel with a fiberglass outer jacket). The UST receives ethylene glycol in the event of a spill from the floor drains throughout the area where ethylene oxide is used and from the deoxx scrubber system, and condensation from the sterilization units. The UST acts as an emergency catch basin if the manufacturing process malfunctions. It was determined, as the piping does not routinely hold product, the secondary containment requirements would not apply. (Note: The facility stated that small quantities of liquid [200 to 400 gallons] are removed from the UST routinely. The same company that empties the 3,000-gallon AST containing ethylene glycol mixture (deoxx scrubber system) also empties the emergency UST. The UST is scheduled for inspection on May 31, 2011.)

Also at the facility is a 3,000-gallon AST which continually processes ethylene glycol solution (approximately 20% ethylene glycol). This AST is part of the deoxx scrubber system; therefore, the AST is exempt from regulation. The facility provided a follow-up letter on June 1, 2000 regarding the exemption of their UST piping and AST, as discussed during the May 31, 2000 PADEP site visit

On June 15, 2000, PADEP sent the facility a letter stating an operations inspection was required for the UST by August 4, 2000. On July 25, 2000, Tank 001 was inspected and compliant. On August 2, 2000, PADEP concurred via a letter.

On July 29, 2005, PADEP sent the facility a letter stating an operations inspection was required for the UST by July 25, 2005. On August 31, 2005, Tank 001 was inspected and compliant. It was noted that the facility had not been keeping the monthly sensor printout or a log of the monitoring system checks. On September 8, 2005, PADEP issued a NOV for the omissions. On October 11, 2005, the facility responded in a letter stating they had taken actions to ensure environmental compliance, including upgrading their leak detection monitoring system. On October 18, 2005, PADEP indicated the violations had been brought into compliance.

On June 4, 2008, an operations inspection was conducted for Tank 001; the UST was compliant. On August 29, 2008 PADEP concurred via a letter.

Investigations and Remedial Actions

According to the facility representatives, there have been no releases and no investigations or remedial actions have occurred at the facility.

Inspections

Waste

On April 17, 1997, both a residual waste inspection and a generator hazardous waste inspection were conducted at the facility by PADEP. The facility handled waste onsite for less than 90 days under PBR. It was noted the facility produced approximately 2,200 pounds of waste per month, making them a LQG. Waste codes identified for offsite disposal included: D001 (waste alcohol), D008 and D039 (waste parts cleaner solvent); D009 and D010 (lab packs, print shop wastes), and F002 (waste rags from the manufacturing process). Source reduction was proposed to the facility. Also, the facility neutralized ethylene glycol process wastewater. The inspection included touring the manufacturing areas, waste accumulation areas, and waste treatment area and reviewing the Preparedness, Prevention, and Contingency (PPC) plan, manifests, a biennial report, residual waste reports, and inspection reports. It was noted that containers holding hazardous wastes should be labeled. No violations were observed.

On June 2, 1998, a generator hazardous waste inspection identified the facility was a LQG generating 26,801 pounds of waste per year. Waste codes identified for offsite disposal included: D008, D018, D039, and D040 (waste parts cleaner solvent); D009, D010, and D011 (mercury thermometers and waste from the print shop); and F002, F003, and D001 (waste alcohol, solvent, and rags from the manufacturing process). No violations were observed.

On September 16, 1999, a generator hazardous waste inspection identified the facility was a LQG. Waste codes identified for offsite disposal included: D001 (waste alcohol); D008, D018, D039, and D040 (waste parts cleaner solvent); D002, D009, and D010 (lab packs and print shop wastes); D001 (waste alcohol); F002 (waste rags from the manufacturing process); and F003 (waste solvent from manufacturing). It was noted that the facility purchased a new chemical storage shed in August 1999. All waste storage was moved outside of the shed at that time to the surrounding area. It was recommended that the facility pave the area around the chemical storage area and slope it to prevent water from running into the area. Also, the facility should update the

waste storage area inspection checklist. No violations were observed.

On February 20, 2001, a generator hazardous waste inspection identified the facility was a LQG. The primary waste codes identified for offsite disposal included: D001 (waste solvent and hydraulic fluid from equipment); D001, D022, F002, F003, U044, and U057 (wastes from the lab); and F002, F003, and D001 (waste rags with MeCl). A follow-up site visit was conducted on March 7, 2001 to review facility records. The waste accumulation storage area contained 13, 55-gallon drums of hazardous wastes (trisodium phosphate crystalline, catch all waste, waste solvent, solvent rags, and expired chemicals), 12 clear bags of waste solvent rags (unlabeled), and an infectious waste "red bag". The storage area was not organized, making it difficult to inspect. During the subsequent site visit, it was discovered that the facility was not conducting weekly inspections of the storage area. In addition, the facility was unable to locate the source reduction strategies for the hazardous waste streams; a copy was requested by the inspector. As a result of the inspection, nine violations were identified and subsequently an NOV letter was issued on March 31, 2001. The nine violations identified included:

- Accumulated wastes more than 90 days
- Failure to manage containers of hazardous wastes
- Failure to keep containers of hazardous waste closed
- Failure to insure proper container configuration and spacing for safe management and access for inspection
- Failure to inspect hazardous waste accumulation storage area weekly
- Failure to insure air emissions standards were being complied
- Failure to mark containers of hazardous wastes with an accumulation date
- Failure to label the waste containers with "hazardous waste" labels
- Failure to label containers of waste to accurately identify the contents

A proposed plan and schedule to correct the violations was required within 14 days. The violations were corrected.

On January 30, 2002, a generator hazardous waste inspection identified the facility was generating the following wastes: F002 (flammable liquid and solid – MeCl); D001 (flammable liquid – IPA, hydraulic oil and mineral spirits); and D001, D002, and D019 (corrosive liquid – acidic, basic, and waste carbon tetrachloride). Documents were reviewed and in order. No

violations were observed.

On July 12, 2002, December 10, 2002, and October 20, 2003, generator hazardous waste inspections identified the facility was generating the following wastes: D001, F002, and F003 (waste flammable solids and liquids, solvents) and D001, D002, and F003 (lab wastes). Hazardous wastes were identified as IPA, MeCl, ethanol, butyl acetate, trichloroethylene (TCE), and phenol. Documents were reviewed and in order. No violations were observed.

On August 3, 2005, a generator hazardous waste inspection identified the facility was generating the following wastes: D001 and F002 (waste flammable solids and liquids, solvents) and D001 and F005 (waste aerosols and waste flammable liquids). Documents were reviewed and in order. No violations were documented.

On January 20, 2010, a generator hazardous waste inspection identified the facility was generating the following wastes: D001, U115, U154, U210, and U220, (flammable liquids, lab packs); and D001, F002, and F003 (flammable liquids and solids, MeCl and IPA [liquid only]). Documents were reviewed and in order. No violations were observed.

C. Description of Exposure Pathways for all Releases or Potential Releases

Air: The facility is located in Allentown, Pennsylvania with a 2009 population of 107,815, according the US Census Bureau (www.factfinder.census.gov, accessed June 23, 2011). B. Braun currently operates under a Title V air permit. Emissions in excess of permit limits are not anticipated under normal operating scenarios.

There is no documentation that any spills or releases occurred at the facility during operations that may have impacted soil and/or groundwater; therefore, vapor intrusion into the onsite and nearby structures from these media is not expected to be a potential exposure pathway at this time.

Groundwater: No site-specific geologic or hydrogeologic investigations have been conducted at the site and no known releases to groundwater have occurred. Based on information obtained from the Pennsylvania Groundwater Information System (PaGWIS, accessed February 10, 2011),

there is one open hole groundwater well located within a 0.5 mile radius of the facility. The well was installed in 1967 for the Bethlehem Steel Company. It is listed as a domestic well with a depth of 140 feet below the ground surface (bgs). As the well is located off Postal Road along the entrance to the airport tarmac, it is unknown if the well is still operable.

According to the Lehigh County property assessment website (accessed March 15, 2011), public water and sewer are used onsite. Water and sewer are provided to the facility and surrounding area by the Catasauqua Municipal Water Works. According to the Borough's 2009 Annual Drinking Water Quality Report, water is derived entirely from three municipally-owned and -operated groundwater wells located within 1,200 feet of the water plant located at Walnut Street and St. Johns Street in Catasauqua. The wells range in depth from 141 feet bgs to 235 feet bgs. The water plant is located approximately 1.6 miles northwest of the facility.

Surface Water/Sediment: Surface water runoff at the facility is directed to storm sewer drains located throughout the property.

Based on information obtained from the PADEP eMapPA website (accessed March 15, 2011), the nearest surface water body to the facility is a tributary to the Lehigh River located approximately 0.5 miles east of the facility. The tributary is designated as a cold water fishery and is listed on the tentative streams integrated list as a non-attaining segment impaired for aquatic life resulting from siltation due to road runoff and storm sewers. The tributary flows to the southwest under US Route 22 where a portion of the stream (approximately 1,800 feet) was enclosed during development of a retail shopping center (Airport Center). The tributary discharges to the Lehigh River approximately 1.2 miles downstream of the facility. At its closest point, the Lehigh River, a designated trout stocking fishery, is located approximately 0.8 miles west of the facility. The Lehigh River is listed on the tentative streams integrated list as a non-attaining segment impaired for aquatic life resulting from siltation due to urban runoff and storm sewers.

Soil: The following soil data is based on information provided by the United States Department of Agriculture (USDA), Natural Resources Conservation Service (NRCS) web soil survey (accessed July 7, 2011). The facility is situated on soils classified as UgB *Urban Land* and UmB *Urban Land Duffield Complex* both with 0 to 8 percent slopes; WaA and WaB *Washington Silt Loam* with slopes of 0 to 3 and 3 to 8 percent, respectively which comprises approximately 82

percent of the soils at the property. The Washington Silt Loam has a hydrologic soil group rating of "B", soils having a moderate infiltration rate when thoroughly wet. These consist chiefly of moderately deep or deep, moderately well drained or well drained soils that have moderately fine texture to moderately coarse texture. These soils have a moderate rate of water transmission.

D. Exposure Pathway Controls and/or Release Controls Instituted at the Facility

Air: B. Braun currently operates under an active Title V air permit (permit number 39-00055) which was issued on January 13, 2010, and is effective through January 12, 2015. Emissions sources included under the permit are two boilers, four emergency generators, two fire pumps, eight sterilizers, the aeration room, the catalytic oxidizer, and the deoxx scrubber system. As discussed earlier, several NOVs were cited but later rescinded by PADEP. There have been no recorded releases to the air; therefore, it is concluded that no exposure pathway or release controls are required for this facility.

The USEPA has requested that the vapor intrusion pathway be evaluated as part of the EI process. The USEPA 2002 *OSWER Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance)* provides a methodology for vapor intrusion evaluation under the current land use conditions using available facility data. It should be noted that the USEPA 2002 guidance is not generally recommended for use in settings that are primarily occupational. However, the PADEP Land Recycling Program *Technical Guidance Manual – Section IV.A.4 (Vapor Intrusion into Buildings from Groundwater and Soil under the Act 2 Statewide Health Standard)* can be applied to both residential and nonresidential receptors. This guidance provides decision matrices for soil and groundwater (under a Statewide Health, generic approach) for determining if indoor air quality may be of concern. Therefore, the PADEP Technical Guidance Manual was used, as deemed appropriate, to evaluate a potential vapor intrusion pathway in this EI report.

There are no known or reported releases at the facility. Therefore, it is not expected that soil or groundwater have been contaminated by the operations conducted at the facility that would create a vapor intrusion issue into the onsite or neighboring buildings. Accordingly, it is concluded that controls are not necessary for the vapor intrusion exposure pathway.

Groundwater: There are no known or reported releases at the facility. Public water and sewer are used onsite. Water and sewer are provided to the facility and surrounding area by the Catasauqua Municipal Water Works. Therefore, it is likely that there are no domestic use wells located downgradient of the facility. Because of these factors, no exposure pathway controls are relevant for the groundwater exposure pathway.

Surface Water/Sediment: B. Braun has a Watershed Protection Permit (Permit No. 07-03) through the Borough of Catasauqua for the disposal of industrial wastewater (including process and water treatment wastewaters from the extruders and water treatment units as well as sanitary wastewater) into the sanitary sewer. The permit is effective through November 9, 2012. There have been no known violations of the facility's Watershed Protection Permit, and no known releases have occurred at the facility. As there are no known or reported releases at the facility, it is concluded that no controls are relevant for the surface water/sediment exposure pathway.

Soil: As there have been no known releases at the facility, and a majority of the property is covered with impermeable surfaces (i.e., buildings, concrete, or asphalt paving), it is concluded that no controls are relevant for the soil exposure pathway.

E. Follow-up Action Items

USEPA Region III will decide if additional information or sampling at the facility is required to determine whether or not the environmental indicators have been met or if corrective action is required for the facility.

APPENDIX A

Photographs

MICHAEL BAKER JR., INC. – PHOTOGRAPHIC RECORD

SITE NAME: B. Braun Medical, Inc.

PHOTOGRAPH **1**	
VIEW **Interior facing northeast**	
PHOTOGRAPHS BY **Baker**	

Comments: Drum Satellite Storage - Solvent rags and RCRA empty drums.

PHOTOGRAPH **2**	
VIEW **Interior facing northeast**	
PHOTOGRAPHS BY **Baker**	

Comments: Storage area for raw isopropyl alcohol, methylene chloride, and cyclohexanone.

MICHAEL BAKER JR., INC. – PHOTOGRAPHIC RECORD

SITE NAME: B. Braun Medical, Inc.

PHOTOGRAPH **3**	
VIEW **Interior facing north**	
PHOTOGRAPHS BY **Baker**	

Comments: Storage area for raw isopropyl alcohol.

PHOTOGRAPH **4**	
VIEW **Interior facing southwest**	
PHOTOGRAPHS BY **Baker**	

Comments: Storage area for raw tetrahydrofuran, methylene chloride, and isopropyl alcohol.

MICHAEL BAKER JR., INC. – PHOTOGRAPHIC RECORD

SITE NAME: B. Braun Medical, Inc.

PHOTOGRAPH **5**	
VIEW **Exterior facing southwest**	
PHOTOGRAPHS BY **Baker**	

Comments: Raw solvent container storage area.

PHOTOGRAPH **6**	
VIEW **Interior facing northeast**	
PHOTOGRAPHS BY **Baker**	

Comments: Hazardous Waste Accumulation Area **-** RCRA empty containers.

MICHAEL BAKER JR., INC. – PHOTOGRAPHIC RECORD

SITE NAME: B. Braun Medical, Inc.

PHOTOGRAPH **7**	
VIEW **Interior facing southwest**	
PHOTOGRAPHS BY **Baker**	

Comments: Hazardous Waste Accumulation Area **-** Waste drum.

PHOTOGRAPH **8**	
VIEW **Interior facing northwest**	
PHOTOGRAPHS BY **Baker**	

Comments: Hazardous Waste Accumulation Area **-** Drums of solvent rags and methylene chloride saturated carbon.

MICHAEL BAKER JR., INC. – PHOTOGRAPHIC RECORD

SITE NAME: B. Braun Medical, Inc.

PHOTOGRAPH **9**	
VIEW **Exterior facing northeast**	
PHOTOGRAPHS BY **Baker**	

Comments: Gated and fenced hazardous waste and raw materials storage area.

PHOTOGRAPH **10**	
VIEW **Interior facing northeast**	
PHOTOGRAPHS BY **Baker**	

Comments: Deoxx Scrubber System Room - Ethylene glycol 3,000-gallon AST.

MICHAEL BAKER JR., INC. – PHOTOGRAPHIC RECORD

SITE NAME: B. Braun Medical, Inc.

PHOTOGRAPH **11**	
VIEW **Interior facing northeast**	
PHOTOGRAPHS BY **Baker**	

Comments: Deoxx Scrubber System Room - Ethylene glycol AST containment trench.

PHOTOGRAPH **12**	
VIEW **Interior facing south**	
PHOTOGRAPHS BY **Baker**	

Comments: Deoxx Scrubber System Room - Ethylene glycol reaction tank.

MICHAEL BAKER JR., INC. – PHOTOGRAPHIC RECORD

SITE NAME: B. Braun Medical, Inc.

PHOTOGRAPH **13**	
VIEW **Interior facing west**	
PHOTOGRAPHS BY **Baker**	

Comments: Raw ethylene oxide drum area.

PHOTOGRAPH **14**	
VIEW **Exterior facing southwest**	
PHOTOGRAPHS BY **Baker**	

Comments: Storage area for empty raw ethylene oxide drums.

MICHAEL BAKER JR., INC. – PHOTOGRAPHIC RECORD

SITE NAME B. Braun Medical, Inc.

PHOTOGRAPH **15**	
VIEW **Exterior facing west**	
PHOTOGRAPHS BY **Baker**	

Comments: Catalytic oxidizer.

PHOTOGRAPH **16**	
VIEW **Exterior facing southeast**	
PHOTOGRAPHS BY **Baker**	

Comments: Catalytic oxidizer.

APPENDIX B

Figures

Source: Google, 2010

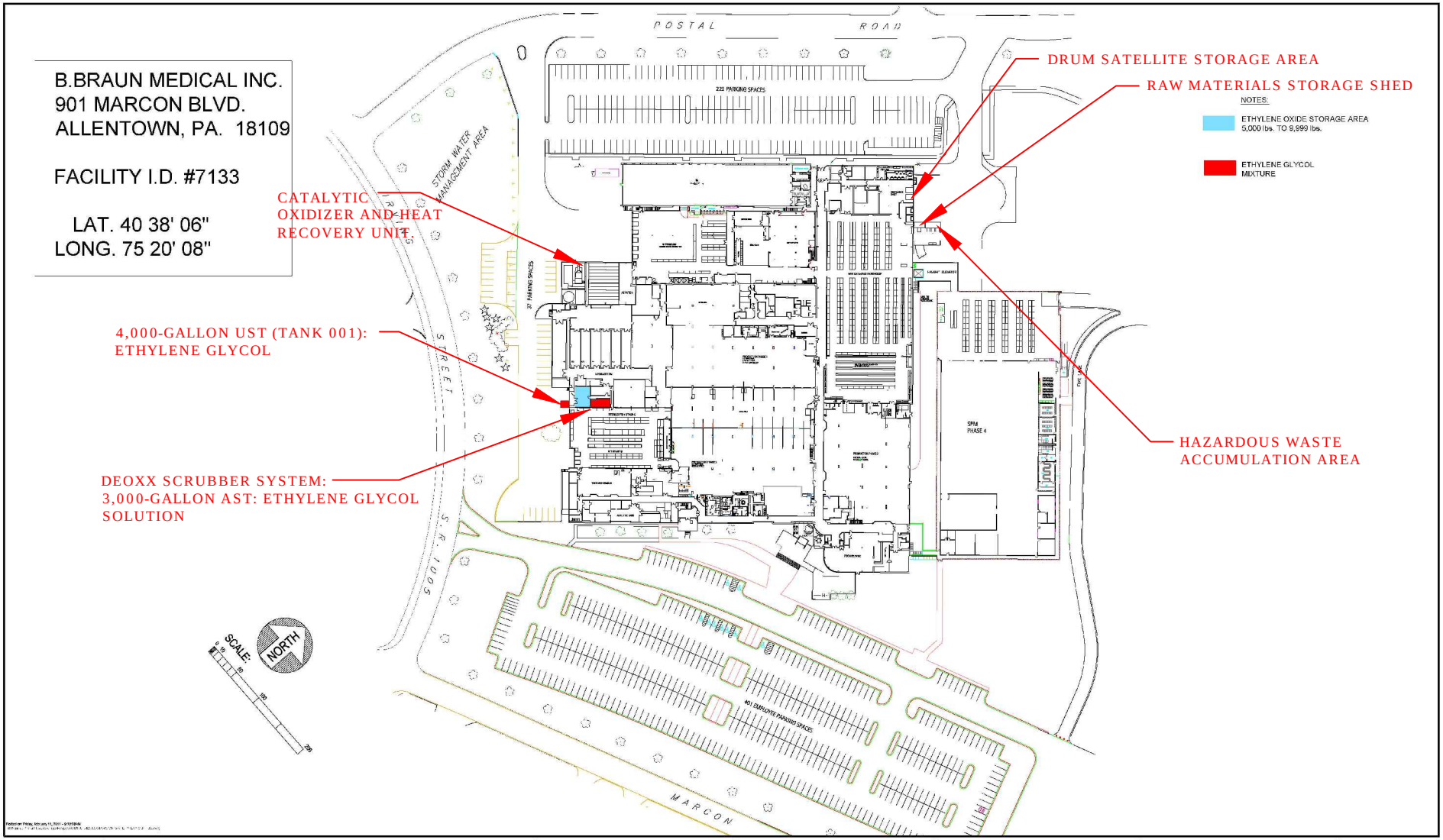
200 0 100 200
1 inch = 200 ft.

SCALE: 1" = 200'	DATE: JULY 2011	Baker MICHAEL BAKER JR., INC.	FIGURE 1
S.O. NO.: 120674	FILE: 120674-BRAUN-01	MOON TOWNSHIP, PENNSYLVANIA	FACILITY LOCATION MAP
DSN/DWN: KT/RRR	CHK: SF		B. BRAUN MEDICAL, INC.
			ALLENTOWN, PENNSYLVANIA

B.BRAUN MEDICAL INC.
901 MARCON BLVD.
ALLENTOWN, PA. 18109

FACILITY I.D. #7133

LAT. 40 38' 06"
LONG. 75 20' 08"



Source: B.BRAUN MEDICAL, 2011 BAKER EDITS. 2011

SCALE: NOT TO SCALE	DATE: JULY 2011
S.O. NO.: 120674	FILE: 120674_BRAUN_02
DSN/DWN: KT/RRR	CHK: SF

Baker MICHAEL BAKER JR., INC.
MOON TOWNSHIP, PENNSYLVANIA

FIGURE 2
FACILITY LAYOUT
B. BRAUN MEDICAL, INC.
ALLENTOWN, PENNSYLVANIA

APPENDIX C

Inventory of Documentation and Reference Documents

The following is a list of documents in the order referenced in the report.

Document Date	Document
June 11, 1990	First Notice of Hazardous Waste Activity
May 5, 1997	Hazardous Waste Activity
April 30, 1997	Neutralization Process Letter
June 6, 1997	PADEP Approves PBR
February 28, 2002	Response to Yearly Compliance Audit
January 14, 2010	Title V PADEP Letter
January 13, 2010	Title V Permit
November 1, 2005	PADEP Rescinds NOV
November 10, 2007	Catasauqua Watershed Permit
May 31, 2000	Storage System Report
June 1, 2000	Exemption Follow Up Letter
June 15, 2000	Tank Inspection Due Letter
July 25, 2000	UST Inspection
August 2, 2000	PADEP Concurrence Letter
July 29, 2005	Tank Inspection Due Letter
August 31, 2005	UST Inspection
September 8, 2005	UST NOV
October 11, 2005	Response to UST Inspection
October 18, 2005	PADEP Letter Citing Compliance
June 4, 2008	UST Inspection
August 29, 2008	PADEP Concurrence Letter
April 17, 1997	Residual Waste Inspection
April 17, 1997	Inspection Hazardous Waste Generator
June 2, 1998	Inspection Hazardous Waste Generator
September 16, 1999	Inspection Hazardous Waste Generator
February 20, 2001	Inspection Hazardous Waste Generator
March 31, 2001	NOV
January 30, 2002	Inspection Hazardous Waste Generator
July 12, 2002	Inspection Hazardous Waste Generator
December 10, 2002	Inspection Hazardous Waste Generator
October 20, 2003	Inspection Hazardous Waste Generator
August 3, 2005	Inspection Hazardous Waste Generator
January 20, 2010	Inspection Hazardous Waste Generator
2009	Catasauqua Annual Drinking Water Quality Report